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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,020	01/16/2004	Charles J. Davidson	S63.2N-12024-US05	5771
490	7590	01/03/2006	EXAMINER	
VIDAS, ARRETT & STEINKRAUS, P.A. 6109 BLUE CIRCLE DRIVE SUITE 2000 MINNETONKA, MN 55343-9185			CHATTOPADHYAY, URMI	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/758,020

Applicant(s)

DAVIDSON ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2004 and 02 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,9-12 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,9-12 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/2/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The Preliminary Amendment filed April 2, 2004 has been entered. The changes to the abstract, specification, drawings and claims have been approved by the examiner. Claims 2, 4-8 and 13-21 have been canceled, and new claim 22 has been added. All pending claims 1, 3, 9-12 and 22 are being considered for further examination on the merits. The formal drawings filed on April 2, 2004 have been approved and entered.

Priority

2. The claims receive priority benefit of parent application 09/669,060 filed September 22, 2000. The claims do not receive priority benefit of provisional application 60/155,611 filed September 23, 1999 because they are not fully supported by the provisional application. The effective filing date of the claims is September 22, 2000.

Information Disclosure Statement

3. The information disclosure statement filed April 2, 2004 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

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The German patent (DE 29701758) and French patent (FR 2678508), which were submitted in the parent application, have not been considered.

4. The new foreign references and non-patent literature documents cited in the IDS, which had not been cited in the parent application, have not been considered because a copy of each reference has not been provided by the applicants. A paper IDS may include a compact disk (CD) that has tables, sequence listings, or program listings. A CD cannot be used to submit copies of patents and publications. See 37 CFR 1.98 and 37 CFR 1.52(e).

Specification

5. The disclosure is objected to because of the following informalities:

a) The first sentence of the specification regarding priority should be changed to indicate that this application is a continuation of 09/669,060, and updated to indicate that 09/669,060 is now U.S. Patent No. 6,689,156.

b) On page 5, lines 8, 9 and 10, page 5, line 22, and page 7, lines 25, 26 and 27, it appears “balloon 25” should be changed to --balloon 20-- because there is no “25” in the Figures.

c) On page 6, line 7, “longitudinal axis 18” must be changed to --longitudinal axis 200-- because “18” has been used to reference guidewire.

d) On page 6, lines 24, 25, 26 and 29, it appears from Figs. 5A and 5B that “signals 16” should be changed to --signals 42--, and also because “16” has been used to reference branch vessel.

e) On page 9, line 21, “filer 350” must be changed to --filter 350--.

f) On page 9, line 26, “side hole 11” must be changed to --side hole 12--.

- g) On page 9, line 26, "branch vessel 14" must be changed to --branch vessel 16--.
Appropriate correction is required.

Claim Objections

6. Claim 12 is objected to because of the following informalities: on line 10, "passageway" should be changed to --passage-- as used on line 6 for consistent claim terminology. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 9-11 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 is indefinite because it requires that both "a *longitudinal* and an *axial* position of an ostium of a branch vessel of said body lumen is determined in relation to said hole". It is unclear what the difference between "longitudinal" and "axial" is. It appears from the specification and page 11, lines 6-8 of the preliminary amendment filed April 2, 2004 that "axial" should be changed to --radial--, and will so be interpreted for examination purposes.

9. Claim 10 is indefinite because it is dependent on claim 7, which has been canceled. The claim therefore, lacks sufficient antecedent basis for the limitation "said passageway" in line 2.

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It appears that the passageway of claim 10 is not the same “multiple passageways” of claim 1 because the invention would otherwise not be enabled by the specification.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1, 3, 9-11 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Von Oepen (USPN 6,048,361 as cited in applicant’s IDS) in view of Jang et al (USPN 5,749,848 as cited in applicant’s IDS).

Von Oepen discloses a stent delivery system for use in a body lumen with all the elements of claim 1, but is silent to an ultrasound transducer being disposed near the catheter body distal end. See Figure 3 for catheter (30) comprising a catheter body having a distal end, proximal end, a longitudinal axis and a lumen, an expansion device (balloon) disposed near the catheter body distal end, and a stent (20) disposed over the expansion device. See Figure 2 and column 2, lines 66-67 for the stent (20) having a wall comprising struts and connectors forming multiple passageways (21) and further comprising a side hole (22) that is adapted to provide access to a side branch. Jang et al. teaches a stent delivery system, which includes an ultrasound transducer (75) disposed inside an expansion device (as required by claim 3) in order to determine exactly where the diseased segment of the blood vessel begins and ends and to image the stent for correct positioning and diameter. See column 4, lines 58-67 and column 8, lines 32-

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35. Jang discloses determining the longitudinal position of a branching segment in column 4, lines 58-67, and as admitted by applicant on page 11, lines 3-7 of the preliminary amendment filed April 2, 2004. Jang also discloses that the ultrasound transducer (75) is fixed to the distal end of a drive shaft (45), and the proximal end of the drive shaft (45) is connected to a drive motor for rotating the drive shaft. See column 9, lines 4-6 and column 10, lines 17-19. Because the ultrasound transducer will rotate with the drive shaft to provide 360 degree imaging, the radial position of the branching segment will also be determined. See column 5, lines 44-60 and column 10, lines 26-39 for the ultrasound transducer (75) being used to image changes in stent diameter, which also clearly indicates the transducer's ability for radial position determination. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Jang et al. to modify the stent delivery system of Von Oepen to include an ultrasound imaging transducer disposed inside the expansion device in order to determine exactly where the diseased segment of the blood vessel begins and ends and to correctly position the stent such that the side hole is positioned at the ostium of a branch vessel. This would replace the completely separate x-ray contrast means and x-ray screen for visual monitoring used by Von Oepen for positioning the side hole, thus simplifying the procedure. In addition, by making the ultrasound transducer adapted to axially translate along and rotate relative to the longitudinal axis, as taught by Jang et al., the examiner contends that use of this ultrasound transducer instead of x-ray will provide the surgeon with more accurate, informative and controllable images of the diseased vessels for side hole positioning.

Claims 9 and 10, see Figure 2 for a guidewire (31) at least partially disposed in the lumen. With respect to claim 10, it is unclear what "said passageway" is referring to.

Claim 11, see column 9, lines 4-6 and column 10, lines 17-19 for a controller in the form of a drive motor being coupled to the transducer (75) via drive shaft (45).

Claim 22, see rejection to claim 1, *supra*. Because the ultrasound imaging transducer (75) allows for the determination of both longitudinal and radial positions of an ostium of a branch vessel, the stent (20) can be delivered within the body lumen such that the side hole (22) can be aligned with the ostium, and thereby meet the functional limitations of the claim.

12. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Von Oepen in view of Jang et al. and Solomon (USPN 5,846,204 as cited in applicant's IDS).

Von Oepen, as modified by Jang et al., discloses a stent delivery system with all the elements of claim 12, but is silent to a transducer housing coupled to the transducer, the housing having distal and proximal ends and a passage through the housing between the ends, and a positioning guidewire at least partially disposed in the catheter lumen and passing through the transducer housing passage. See rejection to claim 1, *supra*. Solomon teaches, in Figure 1, a rotatable ultrasound imaging catheter (100) with a transducer housing (combination of 104 and 108) coupled to a transducer (106) and drive cable (102). Between proximal and distal ends of and through the housing (104 and 108) is a passage (114). A guidewire is accepted through the passage (114) in order to prevent unintended deflection of the transducer as it is rotated around the guidewire for three-dimensional imaging. See column 5, lines 1-14. Because the guidewire sleeve portion (108) is *integral with* the housing portion (104), the transducer housing is rightfully interpreted as including both portions (104 and 108) (column 5, lines 19-22). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to

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the teachings of Solomon to modify the stent delivery system of Von Oepen and Jang et al. to include a transducer housing with a passage coupled to the transducer (75) and drive cable (45) in order to prevent unintended deflection of the transducer as it is rotated around the guidewire disposed in the passage. This ensures that the ultrasound transducer travels in a predetermined path around the guidewire maintained in the passage, which is configured to maintain the planar surface of the transducer substantially parallel with a portion of the guidewire that is located within the passage. See column 6, lines 22-33. By including the housing of Solomon to the transducer and drive cable of Jang et al., the need to remove the guidewire from guidewire/ultrasound lumen (103) before inserting the imaging device with transducer is eliminated. The imaging device with transducer can be positioned directly over the guidewire through the passage and advantageously reduce operating time.

Response to Arguments

13. Applicant's arguments filed April 2, 2004 have been fully considered but they are not persuasive. See the rejections, *supra*, for interpretation of the prior art references.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

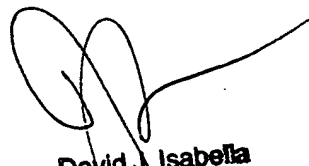
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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David J. Isabella
Primary Examiner